DMB

Display Date 4-27-01
Publication Date 4-30-01
Certifier SREESE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–0788]

Neurological Devices; Reclassification of the Totally Implanted Spinal Cord Stimulator; Denial of Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has denied a petition submitted by Advanced Neuromodulation Systems, Inc. (ANS), to reclassify the totally implanted spinal cord stimulator (SCS) for treatment of chronic intractable pain of the trunk or limbs from class III into class II. FDA had previously made available for public comment the recommendation of the Neurological Devices Panel (the Panel) on the reclassification petition and FDA's tentative findings on the Panel's recommendation. After considering all the available information, including the public comments on the Panel's recommendation, FDA denied the reclassification petition by order in a letter to the petitioner.

ADDRESSES: A copy of the denial order is available at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark N. Melkerson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the 1976 amendments enactment date), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. A postamendment device remains in class III and requires premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

Reclassification of classified postamendments devices is governed by section 513(f)(3) of the act. This section allows FDA to initiate reclassification of a postamendments class III device under

section 513(f)(1) of the act, or a manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order reclassifying the device in class I or class II.

FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of such postamendment class III devices. To change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(3)(B)(i) of the act, the Secretary may, for good cause shown, refer a reclassification petition to a device panel for a recommendation on the subject device's classification. The panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Regulatory History of the Device

The totally implanted SCS intended for treatment of chronic intractable pain of the trunk or limbs is a postamendments device classified into class III under section 513(f)(2) of the act. Therefore, the device cannot be placed in commercial distribution for treatment of chronic intractable pain of the trunk or limbs unless it is reclassified under section 513(f)(2) of the act, or subject to an approved PMA under section 515 of the act.

On June 16, 1999, ANS submitted a petition to FDA that requested reclassification of the totally implanted SCS intended for treatment of chronic intractable pain of the trunk or limbs from class III into class II. Consistent with the act and the regulation, FDA referred the petition to the Panel for its recommendation on the requested reclassification.

III. Device Description

The following device description is based on the Panel's recommendations and the agency's review: The totally implanted spinal control stimulator consists of an implanted pulse generator (IPG), leads, and electrodes. The IPG contains the internal power source that is implanted in the patient. The electrodes are placed on the patient's spinal cord and the leads from the electrodes are connected subcutaneously to the IPG.

IV. Recommendation of the Panel

At a public meeting held on September 16 and 17, 1999, the Panel recommended that the totally implanted SCS intended for aid in the treatment of chronic intractable pain of the trunk or limbs be reclassified from class III into class II. In the **Federal Register** of September 6, 2000 (65 FR 54053), FDA published for public comment a notice of the Panel's recommendation and FDA's tentative findings on the Panel recommendation. FDA invited interested persons to comment by October 6, 2000. In response to a request, FDA later extended the comment period to November 4, 2000.

V. FDA's Decision

FDA received 22 comments in response to the September 6, 2000, notice of panel recommendation. The comments are discussed in detail in the order denying the reclassification petition and in an attachment to that order. Although FDA's earlier tentative findings supported reclassification, the agency has now concluded that class II controls are not adequate to address the risks associated with the device. The most serious risk to health presented by the device is the risk of device failure. Device failure is frequently the result of improper device design. Device failure always requires reoperation with all of the attendant risks of secondary surgery. Many of the comments suggested that general controls and special controls could not adequately control the risk of device failure.

After carefully reviewing the information in the petition, the information presented at the Panel meeting, the Panel's deliberations, the published literature, the Medical Device Reports, and the comments on the notice of panel recommendation, FDA has completed its evaluation of the risks to health associated with the use of the totally implanted SCS intended for treatment of chronic intractable pain of the trunk or limbs.

FDA determined that the petitioner had not demonstrated that special controls would provide reasonable assurance of the safety and effectiveness of the device. Specifically, FDA determined that special controls, such as bench and animal testing, cannot substitute for actual clinical trials designed to demonstrate the safety and effectiveness of these devices. FDA also determined that the risks to health associated with the manufacturing process could only be addressed through the degree of regulatory oversight applied to class III devices. Therefore, on February 23, 2001, FDA issued an order to the petitioner denying the petition for reclassification.

FDA has placed a copy of the order denying the petition on display at the Dockets Management Branch (address above) in the above referenced docket. A copy of the order may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4/18/01
April 18, 2001.

Linda S. Kahan,
Deputy Director for Regulations Policy,
Center for Devices and Radiological Health.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

BILLING CODE 4160–01–S